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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/443,863	11/19/1999	INDU PARIKH	401930/SKYEPHARMA	7862

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EXAMINER	
KISHORE, GOLLAMUDI S	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/443,863	PARIKH ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-52,54-75,77-95,97-104 and 107-131* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-52,54-75,77-95,97-104 and 107-131* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1-31-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The RCE dated 4-6-06 is acknowledged.

Claims included in the prosecution are 50-52, 54-75, 77-95, 97-104, and 107-131.

In view of the terminal disclaimer filed, the double patenting rejection of claims over the claims in the copending application 10/443,772 is withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 50-52, 54-75, 77-95, 97-104, and 107-131 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant now amends the independent claims to recite, "at least two rapidly dispersible matrix-forming bulking/releasing agents, or a combination of a matrix-forming bulking agent and a matrix-forming releasing agent," This is confusing. Does the first part of the expression means two matrix forming bulking agents and two releasing agents?

Similarly, claim 52 recites "two matrix-forming bulking/releasing agents" followed by a Markush group involving several agents in combination. Which members are bulking agents and which members are releasing agents? The expression is very confusing.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 50-52, 54-75, 77-95, 97-104, and 107-131 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/07414 in combination with Green (5,976,577) or Venkatesh (6,475,510).

WO discloses the same process of preparation for the rapidly dispersing oral dosage forms of hydrophobic compounds wherein the particles are coated with at least two surfactants; one of the surfactants is a phospholipid (surface modifying agent). The average particle sizes of the hydrophobic compound are less than 10 microns. The composition contains other claimed materials such as celluloses and mannitol. The process of preparation involves the mixing of the components (water insoluble active agent and the surface modifying agents) in an aqueous medium, sonicating it and lyophilizing the composition to form particles (note the abstract, page 2, line 25 through page 8, line 19, Examples and claims). WO further teaches that the lyophilized powders can be converted into granules or tablets with the addition of binders and other excipients known in the art of tablet making (page 4, lines 14-17). What is lacking in the process of WO is the additional step of adding rapidly dispersible matrix-forming releasing agents to prepare rapidly disintegrating solid dosage form.

Green (5,976,577) discloses fast dispersing solid dosage forms of various drugs. The particles in Green are coated with polymers and lipid materials such as fatty acids (surfactants) and phospholipids. According to Green, the carrier material, which aids the

rapidly disintegrating network, includes microcrystalline cellulose, mannitol, sorbitol and gelatin (abstract, col. 3, lines 43-60, col. 5, lines 30-48, col. 8, lines 20-31, Examples and claims, claim 12 in particular).

Venkatesh similarly discloses fast dispersing solid dosage forms of various drugs. The particles are coated with phospholipids in Venkatesh. According to Venkatesh, the carrier material includes mannitol, sorbitol and xylitol (abstract, col. 5, lines 8-39, col. 6, lines 9-35, col. 7, lines 39-67 and examples).

To add the step of the addition of bulking and releasing agents such as mannitol, microcrystalline cellulose and sorbitol in the method of preparation of WO, if the desired goal is to make the tablets of WO as rapidly disintegrating tablets, would have been obvious to one of ordinary skill in the art at the time the invention was made since the references of Green and Venkatesh each teach that these agents would enable the tables to disintegrate rapidly.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 50-52, 54-75, 77-95, 97-104, and 107-131 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,922,355 in combination with Green (5,976,577) or Venkatesh (6,475,510). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. Claims in the said patent are drawn to a process of preparing microparticles of water insoluble drugs mixing the drug, a phospholipid and another surfactant and applying energy to reduce the particle sizes. Instant claims are drawn to the same process and in addition recite the addition of bulking/releasing agents for the preparation of rapidly disintegrating solid preparation. What is lacking in the patented claims reciting 'comprising the steps of' is the addition of bulking/releasing agents to prepare rapidly disintegrating solid dosage forms.

Green (5,976,577) discloses fast dispersing solid dosage forms of various drugs. The particles in Green are coated with polymers and lipid materials such as fatty acids (surfactants) and phospholipids. According to Green, the carrier material, which aids the rapidly disintegrating network, includes microcrystalline cellulose, mannitol, sorbitol and gelatin (abstract, col. 3, lines 43-60, col. 5, lines 30-48, col. 8, lines 20-31, Examples and claims, claim 12 in particular).

Venkatesh similarly discloses fast dispersing solid dosage forms of various drugs. The particles are coated with phospholipids in Venkatesh. According to Venkatesh, the carrier material includes mannitol, sorbitol and xylitol (abstract, col. 5, lines 8-39, col. 6, lines 9-35, col. 7, lines 39-67 and examples).

To add the step of the addition of bulking and releasing agents such as mannitol, microcrystalline cellulose and sorbitol in the method of preparation of 5,922,355, if the desired goal is to make rapidly disintegrating tablets, would have been obvious to one of ordinary skill in the art at the time the invention was made since the references of Green and Venkatesh each teach that these agents would enable the tables to disintegrate rapidly.

5. Claims 50-52, 54-75, 77-95, 97-104, and 107-131 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,228,399. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. Claims in the said patent are drawn to a process of preparing microparticles of water insoluble drug, cyclosporin by mixing the drug, a phospholipid and another surfactant and applying energy to reduce the particle sizes. . Instant claims are drawn to the same process and in addition recite the addition of bulking/releasing agents for the preparation of rapidly disintegrating solid preparation. What is lacking in the patented claims reciting 'comprising the steps of' is the addition of bulking/releasing agents to prepare rapidly disintegrating solid dosage forms.

Green (5,976,577) discloses fast dispersing solid dosage forms of various drugs. The particles in Green are coated with polymers and lipid materials such as fatty acids (surfactants) and phospholipids. According to Green, the carrier material, which aids the rapidly disintegrating network, includes microcrystalline cellulose, mannitol, sorbitol and gelatin (abstract, col. 3, lines 43-60, col. 5, lines 30-48, col. 8, lines 20-31, Examples and claims, claim 12 in particular).

Venkatesh similarly discloses fast dispersing solid dosage forms of various drugs. The particles are coated with phospholipids in Venkatesh. According to Venkatesh, the carrier material includes mannitol, sorbitol and xylitol (abstract, col. 5, lines 8-39, col. 6, lines 9-35, col. 7, lines 39-67 and examples).

To add the step of the addition of bulking and releasing agents such as mannitol, microcrystalline cellulose and sorbitol in the method of preparation of 6,228,399, if the desired goal is to make rapidly disintegrating tablets, would have been obvious to one of ordinary skill in the art at the time the invention was made since the references of Green and Venkatesh each teach that these agents would enable the tables to disintegrate rapidly. Instant generic term, water insoluble drug includes cyclosporine in the patented claims. Furthermore, it would have been obvious to one of ordinary skill in the art that one could use any drug other than cyclosporin with a reasonable expectation of success since the novelty is in the formulation itself and not dependent upon the drug.

6. Claims 50-52, 54-75, 77-95, 97-104, and 107-131 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,465,016. Although the conflicting claims are not

identical, they are not patentably distinct from each other because of the following reasons. Claims in the said patent are drawn to a process of preparing microparticles of water insoluble drug, cyclosporin by mixing the drug, a phospholipid and another surfactant and applying energy to reduce the particle sizes. Instant claims are drawn to the same process and in addition recite the addition of bulking/releasing agents for the preparation of rapidly disintegrating solid preparation. What is lacking in the patented claims reciting 'comprising the steps of' is the addition of bulking/releasing agents to prepare rapidly disintegrating solid dosage forms.

Green (5,976,577) discloses fast dispersing solid dosage forms of various drugs. The particles in Green are coated with polymers and lipid materials such as fatty acids (surfactants) and phospholipids. According to Green, the carrier material, which aids the rapidly disintegrating network, includes microcrystalline cellulose, mannitol, sorbitol and gelatin (abstract, col. 3, lines 43-60, col. 5, lines 30-48, col. 8, lines 20-31, Examples and claims, claim 12 in particular).

Venkatesh similarly discloses fast dispersing solid dosage forms of various drugs. The particles are coated with phospholipids in Venkatesh. According to Venkatesh, the carrier material includes mannitol, sorbitol and xylitol (abstract, col. 5, lines 8-39, col. 6, lines 9-35, col. 7, lines 39-67 and examples).

To add the step of the addition of bulking and releasing agents such as mannitol, microcrystalline cellulose and sorbitol in the method of preparation of 6,465, 016, if the desired goal is to make rapidly disintegrating tablets, would have been obvious to one of ordinary skill in the art at the time the invention was made since the references of Green

and Venkatesh each teach that these agents would enable the tables to disintegrate rapidly. Instant generic term, water insoluble drug includes cyclosporine in the patented claims. Furthermore, it would have been obvious to one of ordinary skill in the art that one could use any drug other than cyclosporin with a reasonable expectation of success since the novelty is in the formulation itself and not dependent upon the drug.

7. Claims 50-52, 54-75, 77-95, 97-104, and 107-131 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 4-25, 45-47, 52-53, 55-56, 65 and 101-119 of copending Application No. 10/260,788 Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application are drawn to the same process of preparation and the products resulting from said process and the process is directed to water insoluble drugs. Instant claims are drawn to the same process and in addition recite the addition of bulking/releasing agents for the preparation of rapidly disintegrating solid preparation. What is lacking in the patented claims reciting 'comprising the steps of' is the addition of bulking/releasing agents to prepare rapidly disintegrating solid dosage forms.

Green (5,976,577) discloses fast dispersing solid dosage forms of various drugs. The particles in Green are coated with polymers and lipid materials such as fatty acids (surfactants) and phospholipids. According to Green, the carrier material, which aids the rapidly disintegrating network, includes microcrystalline cellulose, mannitol, sorbitol and

gelatin (abstract, col. 3, lines 43-60, col. 5, lines 30-48, col. 8, lines 20-31, Examples and claims, claim 12 in particular).

Venkatesh similarly discloses fast dispersing solid dosage forms of various drugs. The particles are coated with phospholipids in Venkatesh. According to Venkatesh, the carrier material includes mannitol, sorbitol and xylitol (abstract, col. 5, lines 8-39, col. 6, lines 9-35, col. 7, lines 39-67 and examples).

To add the step of the addition of bulking and releasing agents such as mannitol, microcrystalline cellulose and sorbitol in the method of preparation in the copending application, if the desired goal is to make rapidly disintegrating tablets, would have been obvious to one of ordinary skill in the art at the time the invention was made since the references of Green and Venkatesh each teach that these agents would enable the tables to disintegrate rapidly.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments have been fully considered, but are deemed to be moot in view of the above new rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK